In re Application of:

Asakawa and Hasegawa Application No.: 09/762,641

Filed: April 1, 2005

Page 4

PATENT Attorney Docket No.: SHIM1100

REMARKS

Claims 17-21 are currently pending. By the present communication, no claims have been added or canceled, and claims 17 and 18 have amended to define Applicants' invention with greater particularity. Support for the amendments can be found throughout the application as filed. In particular, support for the amendments can be found at, for example, paragraphs 0012 and 0013 of the specification as filed. Accordingly, the amendments do not raise any issue of new matter.

Rejections Under 35 U.S.C. §102

Applicants respectfully traverse the rejection of claims 17-19 and 21 under 35 U.S.C. §102(b) as allegedly being anticipated by Nagai et al. (hereinafter, "Nagai"). Specifically, the Office alleges that Nagai teaches use of (-)RNA viruses to generate ribonucleoprotein complexes that are infectious, capable of autonomous replication and carry foreign genes, but are deficient in disseminative capability due to deletion or inactivation of genes such as the M gene.

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). The Office must show that the single reference cited as anticipatory art describes all the elements of the claimed invention.

Applicants have amended claims 17 and 18 to clarify that only the first cell is inoculated with, or comprises the RNA of interest. Claims 17 and 18 have been further amended to include the step of "detecting the presence of the foreign gene in the second cell." Applicants submit that Nagai is absolutely silent with regard to detection of the foreign gene in the second cell, and therefore cannot anticipate the invention as claimed. Accordingly, Applicants respectfully request that this ground of rejection be withdrawn.

PATENT Attorney Docket No.: SHIM1100

In re Application of:
Asakawa and Hasegawa
Application No.: 09/762,641

Filed: April 1, 2005

Page 5

Rejection of under 35 U.S.C. §103

Applicants respectfully traverse the rejection of claim 20 under 35 U.S.C. §103(a) as allegedly being unpatentable over Nagai in view of Anderson (U.S. Pat. No. 5,399,346; hereinafter, "Anderson") or Quesenberry (U.S. Pat. No. 5,665,350; hereinafter, "Quesenberry"). The Office applies Nagai as described above. However, Nagai does not explicitly teach inoculating the first cell comprising the ribonucleoprotein complex into a mammal. The Office relies upon Anderson and/or Quesenberry for allegedly disclosing the well known and widely practiced method of *ex vivo* gene therapy whereby cells from a subject are genetically modified *in vitro* and subsequently re-introduced into the subject.

To establish a *prima facie* case of obviousness, the Office must show that the prior art would have suggested the claimed invention to one of ordinary skill in the art and that it could have been carried out with a reasonable likelihood of success when viewed in the light of the prior art. *Brown & Williamson Tobacco v. Philip Morris*, 229 F.3d 1120, 1124 (Fed. Cir. 2000), accord In re Royka, 180 USPQ 580 (C.C.P.A. 1974) (to establish *prima facie* obviousness, all claim limitations must be taught or suggested by the prior art); M.P.E.P. §2143.03.

As discussed above, Nagai is absolutely silent with regard to detection of the foreign gene in the second cell. Applicants submit that both Anderson and Quesenberry are also silent with regard to the detection step. Applicants further submit that none of the cited references suggest combining Anderson or Quesenberry with Nagai to arrive at the claimed invention. Thus, one of skill in the art would not have been motivated to combine the references with a reasonable likelihood of success. Even if one of skill in the art were motivated to the combine the references, Applicants submit that it would not result in the claimed invention since all of the references are silent with regard to the detection step. Accordingly, withdrawal of the rejection is respectfully requested.

In re Application of:

Asakawa and Hasegawa Application No.: 09/762,641

Filed: April 1, 2005

Page 6

CONCLUSION

In summary, for the reasons set forth herein, Applicants respectfully submit that the claims clearly and patentably define the invention, and allowance of the claims is respectfully requested. If the Examiner would like to discuss any issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Check number 583872 in the total amount of \$575.00 is enclosed as payment for an Information Disclosure Statement fee (\$180.00) and a Request for Continued Examination fee (\$395.00). Applicant does not believe any other fees are due in connection with the filing of this paper. However, the Commissioner is hereby authorized to charge any fees that may be associated with this communication or credit any overpayment to Deposit Account No. <u>07-1896</u>, referencing the above-identified attorney docket number. A copy of the Transmittal Sheet is enclosed.

Respectfully submitted,

PATENT

Attorney Docket No.: SHIM1100

Date: November 13, 2006

Antony M. Novom, J.D.

Registration No. 45,517 Telephone: (858) 638-6641

Facsimile: (858) 677-1465

DLA PIPER US LLP 4365 Executive Drive, Suite 1100 San Diego, California 92121-2133 USPTO Customer No. 28213